K122125

510(K) Summary

JAN 25 2013

Submitter:	El.En. S.p.A. via Baldanzese, 17 50041 Calenzano (FI), Italy
Contact:	Paolo Peruzzi Regulatory Affairs Manager Phone: +39.055.8826807 E-mail: standards@elen.it
Date Summary Prepared:	November 26, 2012
Device Trade Name:	ASA laser SH1
Common Name:	Nd:YAG Laser System
Classification Name:	Infrared Lamp ILY, 21 CFR 890.5500
Equivalent Devices:	HILT Family Laser **(K051537)**
Device Description:	The ASA laser SH1 is a medical laser system equipped with a Nd:YAG laser source. The Nd:YAG laser radiation has a wavelength of 1064nm and is delivered to the treatment area through a fiber optics and a delivery handpiece connected to its distal end. A warning light is located on the top cover, close to the control panel. Light ON state indicates that the system is enabled and ready. Overall weight of the device is 13 kg, and the size is 38 cm x 22 cm x 42 cm (H x W x D). Electrical requirement is 115Vac 50/60Hz, 750VA.

Indications for Use:	The ASA laser SH1 is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.
Comparison:	The ASA laser SH1 is substantially equivalent to its predicate device. It shares same indication for use, same principle of operation and essentially same technological characteristics and performances.
Nonclinical Performance Data:	None
Clinical Performance Data:	A clinical study has been performed on three live human subjects with three different skin phototypes. The study has shown that ASA laser SH1 is able to induce a skin temperature between 40°C and 45°C and maintain that temperature for at least 10 minutes for all patients.
Conclusion:	The results of clinical performance tests show that ASA laser SH1 system is as safe, as effective and performs as well as its predicate device for the indications for use mentioned above.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EL.EN. Electronic Engineering S.p.A
% Mr. Paolo Peruzzi
Regulatory Affairs Manager
17 Via Baldanzese
Calenzano, Italy 50041

January 25, 2013

Re: K122125
Trade/Device Name: ASA laser SH1
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: November 27, 2012
Received: November 29, 2012

Dear Mr. Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K122125

Device Name: ASA laser SH1

Indications for Use:

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Prescriptive Use X (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence ofCDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off)

Division of Surgical Devices

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